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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/670,861 09/24/2003 Donald A. Schon MED-0005D1 9768

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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02/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/670,861	Applicant(s) SCHON ET AL.	
	Examiner Melanie J. Hand	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-35 and 42-65 is/are pending in the application.
- 4a) Of the above claim(s) 42-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2007 has been entered.

Election/Restrictions

2. Newly submitted claims 42-53 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of step includes the step of cutting an internal septum of a urinary catheter tube to form a first distal end tube and a second distal end tube, a step that is not recited in the methods of claims 22 and 35, which have already been examined on the merits, thereby rendering the method of claim 42 a materially different process from the method of claim 22 and the method of claim 35.

3. Newly submitted claims 54-65 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of independent claim 54 recites the step of attaching first and second distal end tubes to the distal end of the urinary catheter tube such that the first passageway defined by the first distal tube is in communication with the first lumen of the urinary catheter tube and the second passageway is in communication with the second lumen of the urinary catheter tube. This step is not recited in independent claim 22 or independent claim 35 and cannot be practiced with either the method

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of claim 22 or claim 35, thus the method of claims 54-65 is a materially different process from both of the respective methods of claims 22 and 35.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-65 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

4. The declaration under 37 CFR 1.132 filed June 26, 2007 is insufficient to overcome the rejection of claims 22-25, 27-30 and 33-35 under 35 U.S.C. 102 based upon the Ash reference as set forth in the last Office action because: declarant did not state, in addition to being a sole inventor, that the other named inventors in the instant application were working under his direction. See *In re Katz*, 687 F. 2d 450, 215 USPQ 14 (CCPA 1982)

Response to Arguments

5. Applicant's arguments filed June 26, 2007 have been fully considered but they are not persuasive. Applicant argues that the declaration submitted under 37 C.F.R. 1.132 eliminates the Ash reference as a valid prior art reference and that the prior art of Melsky cannot stand alone to anticipate or render obvious the claimed invention. This is not found persuasive because, as stated *supra*, the declaration is insufficient to overcome the rejections under 35 U.S.C. 102 and 35 U.S.C. 103 based upon the Ash reference. A new ground of rejection is made herein based upon the Ash reference.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 22-25, 27-30, 33 and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Ash et al (U.S. Patent No. 5,947,953).

With respect to **Claim 22**: With respect to the step of forming a unitary catheter tube, Ash teaches a double catheter assembly 10 having a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and first and second lumens 28 and 32 separated by a frangible membrane 46 to form a unitary catheter tube defined by the two separable catheters. Each of the first and second lumens necessarily extends through the unitary catheter tube, as the first and second lumens are integral to the unitary tube prior to separation along said membrane. With respect to the step of splitting the unitary catheter tube, Ash teaches partial splitting of septum 46 longitudinally along said distal end portion of assembly 10 to form a first distal end tube 26 and second distal end tube 30.

With respect to **Claims 23,25**: Ash teaches that the catheter assembly 10 has a generally circular cross-section and that the catheters 26,30 have a semi-circular cross section wherein respective flat surfaces 38,44 are facing one another therefore the cross section of assembly 10 would be oval. (Fig. 4F) (Col. 6, lines 1-8, Col. 7, lines 31-35)

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With respect to **Claim 24**: Ash teaches that the cross sections of lumens 28,32 are circular.

(Col. 7, lines 31-37)

With respect to **Claim 26**: Ash teaches that the cannulating portion 20 is formed in a single extrusion process yielding catheters with a semicircular cross section. The single extrusion process includes a step of finishing an exterior of the first and second distal end tubes by virtue of the nature of the process itself, i.e. the molten plastic forming material is drawn through a die which forms the exterior, and positive pressure is applied thereto to form the hollow space of the catheter (the lumen) as an additional step after applying the molten material to the die, thereby casting the molten material into the catheter shape with its semicircular cross section and finished exterior.

With respect to **Claims 27,28**: Please see the rejections of claims 22 and 23 as these rejections collectively address the limitations of claims 27 and 28.

With respect to **Claims 29,30**: Ash teaches separating catheters 26 and 30 along a portion of membrane 46 wherein the length of the split region is greater than the unitary region. (Fig. 1)

(Col. 6, lines 42-45)

With respect to **Claim 33,34**: Ash teaches that the cannulating portion 20 of catheter assembly 10 is formed from an extrusion process. (Col. 12, lines 38-41)

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al ('953).

With respect to **claim 35**: Ash teaches a method of making a multilumen catheter assembly, comprising the steps of: forming a unitary catheter tube in the form of double catheter tube assembly 10 to have a distal portion and a distal end portion terminating in a distal end, a proximal portion terminating in a proximal end, and a first lumen 28 and a second lumen 32. Each of the first and the second lumens 28,32 extends longitudinally through the unitary catheter tube. (Fig. 1) Ash teaches splitting the unitary catheter tube longitudinally via frangible membrane 46 along the distal end portion to form a first distal end tube and a second distal end tube, thereby creating a point of transition between split and unsplit portions of the unitary catheter tube 10, wherein a length of the split portion of the unitary catheter tube, defined as the length from the transition point to the distal end, is greater than a length of the unitary catheter tube from the proximal end to the transition point inasmuch as Ash teaches that the catheters 26,30 defining lumens 28,32 are split along the full length of catheter 10 up to hub 24 (Fig. 1, Col. 11, lines 56-61). The first and the second distal end tubes are separate from the transition point (hub 24) to the distal end, whereby the first and the second distal end tubes are splittable by minimal force via frangible membrane 46 from the transition point to the bonding point and independent and free floating from the bonding point to the distal end.

Ash does not teach releasably re-attaching the first and the second distal end tubes to one another along a partial portion of their longitudinal lengths, the first and the second distal

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end tubes being releasably re-attached from the transition point to a bonding point located between the transition point and the distal end. However, since Ash teaches a configuration where the distal end tubes are separated and a configuration where the distal end tubes are attached, either prior to tunneling into a surgical site or after, it would be obvious to one of ordinary skill in the art to modify the method of Ash to include the step of reattaching (necessarily releasably due to the nature of frangible membrane 46) the first and second distal tubes to one another along a portion of their longitudinal lengths with a reasonable expectation of success to allow easier removal of the catheter assembly from a surgical site.

10. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash ('953) in view of Melsky et al (U.S. Patent No. 5,704,915).

With respect to **Claims 31,32**: Ash does not teach grinding or polishing the cannulating portion 20 of catheter assembly 10. Melsky teaches a hemodialysis access device comprised of a catheter with a proximal and distal end where the distal end is split into two conduits. Melsky teaches pumping a slurry of abrasive material through shells 22 and polishing the subsequently smoothed surfaces of conical shells 22 and outlet tubes 32. Melsky teaches that it is desirable to have blood contacting surfaces be as smooth as possible to avoid thrombus formation and blood cell damage. ('915, Col. 5, lines 13-22) Since the assembly taught by Ash is also used for hemodialysis (Col. 5, lines 42-44), it would be obvious to one of ordinary skill in the art to grind and polish the outside surfaces of the catheter assembly taught by Ash.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 7, 2008

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', is written over the printed name and title of the supervisory primary examiner.